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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,924	05/30/2001	Blake J. Roessler	UM-06191	7554

7590 12/18/2006

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/867,924	ROESSLER ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt amendment and remarks filed 9/25/06. Claims 25-59 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 25-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Although applicant states that the amendment to claim 1 is "located throughout the Specification," the specification as filed does not support providing biological agent to tissues in biologically active concentrations.

Correction is respectfully requested and applicant may point to specific paragraphs of the specification for the support. The new matter rejection may be overcome by deleting the new matter from the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 25-59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Foldvari et al. ("Cutaneous vaccination: the skin as an immunologically active tissue and the challenge of antigen delivery," in Journal of Controlled Release, Volume 66, Issues 2-3, 15 May 2000, Pages 199-214) and Baker et al. ("Regulation of in vivo gene expression using antisense oligonucleotides or antisense expression plasmids transfected using starburst PAMAM dendrimers," in Nucleic Acids Research, 1996, Vol. 24, No. 11, pp 2176-2182) in view of Park et al. (US 6,267,987)

5. Foldvari discloses transdermal delivery of protein or nucleotide to the skin tissue (pp. 71-86). Foldvari discloses on page 205 that dendrimers are known to deliver DNA. Baker discloses the use of dendrimers to deliver DNA (pp 2176-2182).

The combination of Foldvari and Baker discloses the use of dendrimers for the delivery of proteins or DNA. The combined reference failed to disclose the presence of polyester for the delivery. But Park discloses polyesters as carriers for delivery of nucleic acids (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teaching of Foldvari and Baker for the delivery of DNA or protein. One having ordinary skill in the art would have been motivated to incorporate polyesters with dendrimer and expect to successfully deliver DNA.

Response to Arguments

6. Applicant's arguments filed 9/25/06 have been fully considered but they are not persuasive.

Applicant argues that there is no motivation to combine the references. That "both the suggestion and the expectation of success must be founded in the prior art and not the applicant's disclosure." That the amendment to claim 1 now in part reads "...such that said biological agent is provided to said tissue at biologically active concentrations." That the cited references provide no expectation of success where tissues contacted with a composition would be provided with a biologically active agent.

Response:

Foldvari discloses cutaneous vaccination (title). The skin (paragraph 2) through which the vaccine is administered reads on the tissue of the claims. Foldvari discloses dendrimers that are complexed with DNA in spherical structures and the dendrimers and the DNA can be delivered to cell lines (right column, first full paragraph of page 205). Acrylate, PAMAM and polyethyleneimine polymers are some of the polymers listed that are used with the DNA (right column, page 205). Furthermore, Foldvari discloses the use of PLGA, PLA, lactides and glycolides for delivery of protein, carbohydrate or DNA vaccines (right column, page 204). These polymers are biocompatible and biodegradable. Liposomes are also used to deliver beneficial agents (paragraph 3.4). Baker discloses the use of PAMAM dendrimers for effective delivery of oligonucleotides evaluated in vitro cell culture system (abstract, right column of page 2177). Park discloses polyester based dendrimer system for delivery of oligonucleotides

(abstract; column 2, lines 3-5, 36-40; column 3, lines 24-34; column 4, lines 1-46; column 9, lines 8-17).

Therefore, the motivation to combine the references flows from teaching in the references that oligonucleotides are deliverable by dendrimers that are composed of polyesters (Foldvari and Park) and expected to successfully deliver the nucleotides to the tissues that are contacted with the dendrimer (abstract of Baker). Therefore, the cited references provide methods where the tissue and dendrimer compositions are brought into contact for the delivery of oligonucleotide. Regarding "active concentrations" in the phrase "contacting said tissue with said composition such that said biological agent is provided to said tissue at biologically active concentrations," it is noted that active concentration reads on any amount and since the prior art delivers oligonucleotide to tissues or cells, the prior art would meet any amount within the broad active concentrations claimed.

Regarding claim 26, Baker describes transfer of oligonucleotides in cell culture (abstract).

Regarding biocompatible membrane of claim 32, 33 and 35, Foldvari describes microencapsulation in polyester membranes (microspheres, liposomes) and the polyesters are bioerodible.

Regarding the collagen of claim 36, it would be obvious to substitute one membrane material for another and still expect effective delivery of the nucleotides. For example, collagen is an essential protein, which can be found in skin, connective tissue, blood vessels, bone and other parts of the body and collagen and PLGA have been used as membrane materials with dendrimer to deliver DNA (see abstract of Bielinska et al. "Application of membrane-based

dendrimer/DNA complexes for solid phase transfection in vitro and in vivo" in Biomaterials, Vol.21, Issue 9, May 2000, pages 877-997, as a teaching reference).

Regarding claim 43, DNA according to claims 44 and 45 is a therapeutic agent and the prior art thus discloses therapeutic agent of claims 43-45.

Wound healing, encoding growth factor, tissue vascularization, protein are all functions of DNA; protein that comprises protein that promotes tissue vascularization is the function of the protein. Thus claims 43, 46, 47, 48, 49, 51, 52, 53 and 54 are met.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara BF
Patent Examiner
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER